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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,274	07/30/2001	Jean Francois Michelet	P66901US0	8035

7590 06/18/2003

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WASHINGTON, DC 20004

EXAMINER

YU, GINA C

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 06/18/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/917,274

Applicant(s)

MICHELET ET AL.

Examiner

Gina C. Yu

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Receipt is acknowledged of Amendment filed on April 2, 2003. Claim rejections under 35 U.S.C. §§102 and 103, as indicated in the previous Office action dated October 2, 2002 are withdrawn in view of applicants' remarks. Claim rejection Claim rejection under § 112, first paragraph, is maintained in part for the reasons of record. Obviousness double patenting rejection is withdrawn in view of the abandonment of the cited co-pending application 09/917211. Claims 1-20 are pending.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as containing ~~subject matter which was not described in the specification in such a way as to enable~~ one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants' specification and prior art do not enable (1) method of attenuating, reducing or stopping the growth of hair by using the claimed composition; (2) method of stopping the growth of hair. The specification and prior art do not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with this claim without undue experimentation.

Factors to be considered in determining whether any necessary experimentation is "undue" include, but are not limited to: the breadth of the claims; the nature of the

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invention; the state of the prior art, the level of one of ordinary skill; the level of predictability in the art; the amount of direction provided by the inventor; the existence of working examples, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. See In re Wands, 858 F.2d 731, 737, 8 U.S.P.Q. 2d 1400, 1404 (Fed. Cir. 1988).

(1) The enablement for "a method for attenuating, reducing or stopping the growth of hair" using prostaglandin EP3 receptor agonists such as PGE1 also lacks support from the prior art. It is well known in the art that prostaglandin PGE1 actually promotes human hair growth. See Katsu abstract (CAPLUS Acc. No. 1987:55617). Undue experimentation is necessary to determine to demonstrate the efficacy of the presently claimed invention, which is inconsistent with the prior art teaching.

(2) Applicants' disclosure also fails to enable the claimed method of "stopping the growth of hair". The burden of enabling the prevention of a natural condition such as the growth of hair (i.e., the need for additional testing) would be greater than that of enabling a treatment due to the need to screen the subjects for prolonged period of time. In the instant case, the specification does not provide guidance as to how one skilled in the art would go about stopping the growth of hair within the scope of the presently claimed invention. Nor is there any guidance provided as to a specific protocol to be utilized in order to prove the efficacy of the presently claimed method in preventing the hair growth. Undue experimentation is necessary to determine screening and testing protocols to demonstrate the efficacy of the presently claimed method.

Applicants argue that the claims are enabled by the disclosure in the specification. Applicants refer to the example data showing daily application of a "prostaglandin PGE1 by a specific amount reduces the daily growth of the hair, and asserts that the data indicates a surprising results contrary to the prior art teaching. Examiner respectfully disagrees. Prior arts such as Katsu abstract (CAPLUS Acc. No. 1987:55617 and Hanson (US 5605931) teach one having ordinary skill in the art that prostaglandin EP-3 is a well-known hair growth agent. Examiner takes the position that claimed the method of using the same compound for the exact opposite purpose does not render the invention nonobvious but rather necessitates undue experimentation to determine the efficacy of the claimed invention.

Applicants also assert that applicants' disclosure shows a "marked reduction in the daily growth of hair". Examiner takes the position that the claimed method of "stopping the growth hair" however is not enabled by the disclosure and a skilled artisan would not have been able to make or use the invention without undue experimentation.

#### ***Response to Arguments***

Applicant's arguments filed on April 2, 2003 have been fully considered but they are not persuasive in part, as discussed above.

#### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

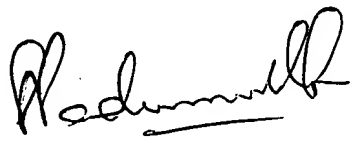
TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina C. Yu  
Patent Examiner  
June 16, 2003

  
SREENI PADMANABHAN  
PRIMARY EXAMINER  
6/16/03